5. 510(k) Summary

(per 21 CFR 807.92)

APR 2 4 2013

08 November 2012

Sponsor
Mr. Sailor Mohler
Quality Manager
Zephyr Technology Corporation
1 Annapolis Street, Suite 200
Annapolis MD 21401 USA
Office: 443-569-3603
sailor.mohler@zephyranywhere.com

Consultant
Mr. Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, CT 06907-1659
203 329 2700 F 203 329 2345
rkeen@fda-complianceconsultants.com

Proprietary Name:	BioModule 3-M1
Common Name	BioModule 3-M1
Device Classification Name	(1) Electrocardiograph Electrode (2) Arrhythmia Detector and Alarm
Classification Number:	(1) 21CFR870.2360 (2) 21CFR870.1025
Product Code	(1) DRX (2) MHX
Reviewing Group	Cardiovascular
Device Classification	Class II
Establishment registration No.	# 233836
Predicate Device	**Zephyr Technology, *BioHarness 3.0*, K113045, transmits physiological data in a complex array of packet data.**

Trademark Notice: All Trademarks used other than those of Zephyr Technology Corporation are registered to their respective owners.

Confidentiality Notice: All data contained in this application and all documents provided with this document may contain trade secrets or proprietary data which the sponsor requests are treated in accordance with law.

Device Description

The BioModule 3-M1, a physiological sensor / transmitter is composed of:

- proprietary hardware and firmware, enclosed in
- a user case (puck) with a re-chargeable battery,
- a adhesive electrode set and
- A cradle (to recharge battery and transfer internally stored date to an ancillary computer).

The BioModule 3-M1 is a physiological transmitter manufactured by Zephyr Technology Corporation with disposable, off the shelf electrodes that transmits data to a qualified receiving station. The BioModule 3-M1 is positioned against the patient's skin with light pressure then pressed to adhere.

Indications for Use

The BioModule 3-M1 is a physiological monitoring telemetry device intended for monitoring ambulatory patients in alternate care settings. The device consists of adhesive electrodes and an electronics module. The device stores and transmits vital sign data including ECG, heart rate, respiration rate, body orientation

5. 510(k) Summary

(per 21 CFR 807.92)

and activity. The BioModule 3-M1 provides a facility to detect and transmit single lead ECG signals to be received by qualified instruments.

The BioModule 3-M1 collects and transmits measurements captured in alternate care settings as prescribed by the health care professional. Breathing rate values are accurately transmitted only during sedentary periods.

The BioModule 3-M1 is indicated for use as a general patient monitor to provide physiological information as part of general ward monitoring system.

Intended Use

The **intended use** of the BioModule 3-M1 is to provide a General Ward Monitoring facility for detecting, storing and transmitting physiological date to a qualified receiving station. The **scientific concept** on which this device is based is the principle that low level electrical pulses from the heart are measurable of the surface of the skin. This device **functions** by capturing these electrical pulses via electrodes and delivering these signals to sophisticated electronics for processing. The calibration is established by the factory and yields accurate and calibrated signals that can maintain calibration over its useful life.

Substantial Equivalence

Zephyr Technology Corporation has determined that the BioModule 3-M1 is substantially equivalent to the performance of a predicate Device, BioHarness 3.0 [K113045]. The differences between these systems are incidental and not significant. Both devices use a similar technological characteristics and principles.

- Both devices use electrodes to capture signals from the skin,
- both devices convert analog physiological signals to digital signals,
- both devices use micro-processors, firmware and signal processing,
- both devices transmit the signals to receivers that detect and present the information as ECG waveforms.

Safety and Effectiveness

There are no substantial differences between the BioModule 3-M1 and the predicate Device, BioHarness 3.0 [K113045]. BioModule 3-M1 defined in this 510(k) submission and the predicate device are virtually identical except minor changes for use in a different marketplace.

This device is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy. A series of factory tests are conducted to verify the intended signals are accurate and can maintain a calibrated energy pattern over its useful life. The BioModule 3-M1 has benefited from design, development, testing and production procedures that conform to Quality Systems.

Zephyr Technology Corporation continues to search all appropriate sources for information relating to safety and effectiveness and maintains an *in-house* reporting device to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 24, 2013

Zephyr Technology Corporation
c/o: Richard Keen (Agent)
Compliance Consultants
1151 Hope Street
Stamford, CT 06907-1659

Re: K123658
Trade Name: Biomodule 3-M1
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph electrode
Regulatory Class: Class II
Product Code: DRX
Dated: February 28, 2013
Received: March 15, 2013

Dear Richard Keen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(K) Number number assigned__ Name: *Respiration Rate Upgrade (RRU)*

INDICATIONS FOR USE

The BioModule 3-M1 is a physiological monitoring telemetry device intended for monitoring ambaltory patients in alternate care settings. The device consists of adhesive electrodes and an electronics module. The device stores and transmits vital sign data including ECG, heart rate, respiration rate, body orientation and activity. The BioModule 3-M1 provides a facility to detect and transmit single lead ECG signals to be received by qualified instruments.

The BioModule 3-M1 collects and transmits measurements captured in alternate care settings as prescribed by the health care professional. Breathing rate values are accurately transmitted only during sedentary periods.

The BioModule 3-M1 is indicated for use as a general patient monitor to provide physiological information as part of general ward monitoring system.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)		
Prescription Use ____XXX_____	**or**	**Over - The - Counter Use** _____ **(Per 21 CFR 801.109)**
		(Optional Format 1-2-96

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
2013.04.24
15:47:21 -04'00'